

**REMARKS**

This amendment is submitted in response to the Office Action mailed January 26, 2009, in connection with the above-identified application (hereinafter, the "Office Action") and the Notice to Non-Compliant Amendment mailed July 13, 2009 (hereinafter, the "Notice"). The Notice provided a one-month shortened statutory period in which to respond, ending on August 13, 2009. Accordingly, this amendment is timely submitted. Although the Applicant believes that no fees are due at this time, the Commissioner is hereby authorized to charge Deposit Account No. 50-4498 in the name of Nestle Nutrition for any fees that maybe deemed owed or credit any overpayment related to the above-identified application.

**I. Pending Claims**

Claims 22, 24-30, 32, 33, 35-38, 45-47 and 52-55, as amended, and new claims 56-63 appear in this application for the Examiner's active consideration. Claims 25 and 33 has been amended to recite "...10% by weight of the total weight of the composition," as suggested by the Examiner. Claims 22 and 30 have been amended to recite that the viscosity-lowering protein is present in an amount to lower the viscosity of viscous soluble fibers in the composition to less than about 500 mPas at room temperature such that the composition is less viscous than the same composition in which the viscosity-lowering protein is absent to facilitate administration thereof, support for which is found throughout the specification, e.g., in paragraph [0016] of the published application. Claim 52 has been amended to correct a typographic error. Applicant respectfully submits that no new matter has been introduced by these amendments. Therefore, all amendments should be entered at this time.

Claims 19-21, 29, 38-41 and 44-51 were withdrawn. To facilitate prosecution, claims 19-21 and 39-44 have been cancelled at this time. Claims 29, 38, and 45 have been amended to depend from non-withdrawn claims so that it is believed that these claims, as well as claims 46 and 47 which depend from claim 45, should be rejoined. Also, claims 48-51, directed to methods of using the claimed compositions, have been re-written as new claims 56-63. These method claims are withdrawn at this time, but it is understood that they will be rejoined when the pending composition claims from which they depend are allowed. As to the cancelled claims and to the extent that the withdrawn claims are not rejoined, Applicant reserves the right to

pursue patent protection for the subject matter of these claims in a divisional or continuation application.

Applicant does not acquiesce in the correctness of the rejections or objections, and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Applicant has fully considered the Office Action and the cited references and submits this Reply and Amendment in response to the outstanding objections and rejections. Applicant respectfully submits that the objections and rejections based on indefiniteness, lack of novelty and obviousness are overcome in view of the amendments and arguments presented in the response. Applicant, therefore, respectfully requests that all amendments be entered at this time and reconsideration of this application for patent in view of the above amendments and the following remarks presented hereinbelow.

## **II. Claim Objection**

Claims 22, 24-28, 30, 32, 33 and 35-37 have been objected to for informalities. Applicant respectfully submits that the recitations of “one or more viscous soluble fiber(s) and ...protein(s)” in these claims are not due to typographical errors, as alleged by the Examiner. Such claim language is commonly used and readily understood by the general public. In particular, “fiber” and “protein” are singular when there is only one fiber or one protein present and plural when there are more than one fibers or more than one proteins present. Therefore, the objection has been overcome and should be withdrawn.

## **III. Rejection under 35 U.S.C §112, Second Paragraph**

Claim 33 has been rejected under 35 U.S.C §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, the phrase “based on” in claim 33, as well as claim 25, has

been replaced by "by weight of" as suggested by the Examiner. Therefore, this rejection has been overcome and should be withdrawn.

**IV. Rejection under 35 U.S.C §102(b)**

Claims 22, 26-28, 30 and 35-37 have been rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 6,210,686 to Bell et al. (referred to hereinafter as "Bell"). Applicant respectfully disagrees with the rejection. Bell discloses dietary supplements comprising yeast-derived fiber such as glucan and glucomannan, folic acid or a salt thereof, vitamin B<sub>6</sub>, vitamin B<sub>12</sub> and vitamin E (see the Abstract of Bell). Bell's dietary supplements are for lowering the risks of heart diseases and for improving cardiovascular health in humans. Although the dietary supplements disclosed in Bell may further include proteins, these proteins are selected as a result of their high biological value, i.e., having a high proportion of the essential amino acids (see col. 5, ll. 46-48 of Bell). Bell does not teach or even suggest that these proteins have the ability to lower the viscosity of viscous soluble fibers or that they should be added in an amount sufficient to achieve that purpose. In contrast, the present claims as amended recite that one of the key features of the composition of the present invention is that "said composition is less viscous than the same composition in which the viscosity-lowering protein is absent." Moreover, the composition of the present invention as claimed also requires that the one or more viscosity-lowering protein(s) is moderately hydrolyzed, which is neither taught nor suggested by Bell. Furthermore, as conceded by the Examiner, Bell is silent regarding the selected species (see page 4, ll.3-4 of the Office Action). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As Bell fails to expressly or inherently disclose each and every element of the present invention as claimed, in particular, the ability of the viscosity-lowering protein to lower the viscosity of the viscous soluble fiber in the composition, Bell does not anticipate or render obvious the present invention as claimed. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection.

Claims 22, 26-28, 30 and 35-37 have been rejected under 35 U.S.C. §102(b), as being anticipated by Australian Patent Application No. AU 9873118 A to Jaussan et al. (referred to

hereinafter as "Jaussan"). Applicant respectfully disagrees with the rejection. Jaussan generally describes a nutritional composition for diabetic patients which includes a protein source, a lipid source, a carbohydrate source and a fiber mixture that includes a viscous soluble fiber and inulin, a hydrolysate of inulin or both. The goal of Jaussan's composition is to increase the viscosity of the contents of the stomach and the small intestine. This is directly contrary to the purpose of the claimed composition, i.e., to provide a non-viscous composition that can be enterally or orally administered to a human. As pointed out in the specification, high viscosity may render problematic the preparation of a composition for oral or enteral administration (see paragraph [0004] of published application). In addition, the claimed compositions do not require inulin or its hydrolysates, which are indispensable for the composition of Jaussan. Thus, the composition of the present invention is completely different from that of Jaussan. More importantly, Jaussan does not teach or suggest all the recited features of the claimed compositions, in particular, the ability of the viscosity-lowering protein to lower the viscosity of the viscous soluble fiber in the composition such that the claimed composition is less viscous than the same composition in which the viscosity-lowering protein is absent. Accordingly, Applicant respectfully submits that Jaussan fails to anticipate or render obvious the claimed compositions, as set forth in claims 22 and 30 as amended, as well as the claims that depend therefrom. Reconsideration and withdrawal of the rejection are earnestly requested.

Claims 22, 25-27, 30, 33, 35 and 36 have been rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 6,589,511 to Shimizu (referred to hereinafter as "Shimizu"). Applicant respectfully disagrees with the rejection. Shimizu generally describes a composition for forming solid particles that include a biodegradable polymer, a solvent, a polyhydric alcohol, a viscosity increasing agent and an active drug, wherein the composition is in form of an emulsion. Shimizu's composition can be used in the treatment of or as a prophylactic for periodontal disease or gingivitis. Shimizu fails to teach or suggest that the composition is less viscous due to the presence of the viscosity-lowering protein, as recited and claimed in the present claims as amended. To the contrary, Shimizu actually teaches away from the presently claimed invention by requiring a viscosity increasing agent to increase the viscosity of the composition instead of lowering it, as required by the claimed composition. As Shimizu fails to disclose each and every element of the present claims, it does not anticipate or render obvious

the present invention as claimed. In view of the amendments and remarks presented herein, reconsideration and withdrawal of the rejection in view of Shimizu are respectfully requested.

Claims 22, 25-27, 30, 33, 35 and 36 have been rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,470,839 to Laughlin et al. (referred to hereinafter as "Laughlin"). Applicant respectfully disagrees with the rejection. Laughlin generally describes a composition and method for providing nutrition to a diabetic patient, wherein the composition is a low carbohydrate and a high fat formulation (particularly medium chain triglycerides) (see the Abstract of Laughlin). Although the composition of Laughlin may further include a protein source (e.g., casein, whey protein, or non-fat milk) and a dietary fiber, Laughlin does not teach or suggest that the protein is a moderately hydrolyzed viscosity-lowering protein that is capable of lowering the viscosity of the viscous soluble fibers in the composition, or that such protein should be present in an amount sufficient to reduce the viscosity of the composition, as presently claimed. As Laughlin fails to disclose each and every element of the present claims, it does not anticipate or render obvious the present invention as claimed. Accordingly, Applicant again respectfully requests the reconsideration and withdrawal of the rejection in view of Laughlin.

Claims 22-28, 30, 32, 33 and 35-37 have been rejected under 35 U.S.C §102(b) as being anticipated by European Patent Application No. 0323510 A1 to Ohta et al. (referred to hereinafter as "Ohta"). Ohta generally describes a food composition which includes water-soluble edible fibers (e.g., carageenan and guar gum) and proteins (e.g., casein or its salts) having isoelectric point in an acidic region in such a content that an aqueous solution of the composition gels when in contact with the gastric juice (see the Abstract of Ohta). Ohta is silent regarding the key features of the present invention as claimed, e.g., the composition is less viscous due to the presence of the viscosity-lowering protein. Moreover, Ohta actually teaches away from the presently claimed invention by reducing temperature or pH to increase the viscosity of the composition instead of lowering it, as required by the claimed compositions. As Ohta fails to disclose each and every element of the present claims, it does not anticipate or render obvious the present invention as claimed. In view of the amendments and remarks presented herein, reconsideration and withdrawal of the rejection in view of Ohta are respectfully requested.

Claims 22, 26-28, 30 and 35-37 have been rejected under 35 U.S.C §102(b) as being anticipated by U.K. Patent Application No. 2021948 A to Heath et al. (referred to hereinafter as "Heath"). Heath generally describes the use of gums in therapy for the reduction of cholesterol and/or glucose level in the blood. Examples of gum include guar gum, pectin, locust bean gum and alkyl celluloses. The fine particles of the gum are coated with a layer of substance (e.g., protein) having a greater tendency to absorb water than the gum. However, Applicant respectfully submits that Heath's water-miscible gum compositions are different from that of the claimed invention. On the one hand, Heath fails to teach or suggest a composition that is less viscous than the same composition in which the viscosity-lowering protein is absent, as presently claimed. On the other hand, the composition of the present invention as claimed also requires that the one or more viscosity-lowering protein(s) is moderately hydrolyzed, which is neither taught nor suggested by Heath. Because Heath fails to disclose or suggest each and every element of the present invention, as presently claimed herein, Applicant respectfully requests the reconsideration and withdrawal of the rejection in view of Heath.

Lastly, Claims 22-28, 30, 32, 33 and 35-37 have been rejected under 35 U.S.C §102(b) as being anticipated by U.S. Patent No. 6,355,609 to Mallangi et al. (referred to hereinafter as "Mallangi"). Mallangi generally describes nutritional solutions (e.g., enteral) and methods of making such solutions that include protein, lipid, a carbohydrate source including high amylase starch and guar gum (see the Abstract of Mallangi). According to Mallangi, stability of the nutritional solutions can be improved by providing a stabilizing combination of starch and gum (Mallangi, at column 3, lines 47-67), and that addition of guar gum or Carageenan to a starch formula would increase viscosity (Mallangi, at column 6, lines 59-65). This is completely contrary to the claimed composition, wherein one or more moderately hydrolyzed viscosity-lowering proteins are added to lower the viscosity of the viscous soluble fibers in the composition prior its oral or enteral administration to a subject. As noted above, the present specification teaches that high viscosity may render problematic the preparation of a composition for oral or enteral administration (see paragraph [0004] of published application). Thus, Mallangi fails to teach or suggest all the recited features of the claimed compositions, in particular, the ability of the viscosity-lowering protein to lower the viscosity of the viscous soluble fiber in the composition such that the claimed composition is less viscous than the same composition in which the viscosity-lowering protein is absent. In view of the claim amendments and remarks

presented herein, claims 22-28, 30, 32, 33 and 35-37 are patentable over Mallangi.

Reconsideration and withdrawal of the rejection are respectfully requested.

Applicant respectfully requests that all of the §102 rejections be reconsidered and withdrawn at least in view of the arguments and claim amendments set forth hereinabove, and further in view of additional arguments presented hereinbelow.

**V. Rejection under 35 U.S.C §103(a)**

Claims 22, 24-28, 30 32, 33, 35 and 36 have been rejected under 35 U.S.C §103(a) as being unpatentable over U.S. Patent No. 3,889,007 to Gunter et al. (referred to hereinafter as “Gunter”) or US patent No. 4,478,658 to Wittwer (referred to hereinafter as “Wittwer”).

Applicant respectfully traverses this rejection. Gunter discloses a food composition for aquatic organisms comprising fish meal and fish extracts. Although the composition of Gunter may further include a fiber and a protein, Gunter fails to teach that the protein is moderately hydrolyzed and is capable of lowering the viscosity of the fiber in the composition such that the composition is less viscous than the same composition in which the protein is absent, as presently claimed. Thus, Gunter does not teach or suggest the present invention as claimed, and Wittwer does not remedy the deficiencies of Gunter.

Wittwer discloses that a method for sealing edible capsules comprising telescopically engaged tubular capsule halves that define a junction seam between them. Although Wittwer discloses a film forming material that may be selected from the group consisting of proteins and fibers and mixtures thereof, like Gunter, it fails to teach or suggest that the protein is moderately hydrolyzed and is capable of lowering the viscosity of the fiber in the composition such that the composition is less viscous than the same composition in which the protein is absent. Applicant respectfully submits that the Examiner erred in alleging that features not expressly taught by Gunter or Wittwer “is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.” First and foremost, the key features of the composition of the present invention, i.e., the protein is moderately hydrolyzed and is capable of lowering the viscosity of the fiber in the composition such that the composition is less viscous than the same composition in which the protein is absent, are the discovery of the inventors of the present invention. As evident by the previous analysis of the numerous references cited by

the Examiner, none of these references recognize the advantages that are achievable in the use of a low viscosity composition for oral or enteral administration so that those references cannot teach or suggest the features of the present invention. Thus, the state of the art is such that, in the absence of the teachings from the present invention, one skilled in the art would not know how to make a composition as recited and claimed in the present claims comprising one or more viscous soluble fiber(s) and one or more viscosity-lowering protein(s), wherein said one or more viscosity-lowering protein(s) has the ability to lower the viscosity of viscous soluble fibers in the composition such that said composition is less viscous than the same composition in which the viscosity-lowering protein is absent.

Since Gunter and Wittwer, either alone or in combination, do not teach or suggest the present invention as claimed, they do not render the present claims obvious. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection in view of Gunter and Wittwer.

Claims 22-28, 30, 32, 33 and 35-37 are rejected under 35 U.S.C §103(a) as being unpatentable for obviousness over U.S. Patent No. 6,287,623 to Nakayama et al. (referred hereinafter as "Nakayama"). Applicant respectfully traverses this rejection.

Nakayama generally describes a method for producing a protein-containing acid food and drink that includes a protein emulsion having a pH value that is higher than the isoelectric point of the protein in the emulsion at high temperature to make the emulsion having a pH value that is lower than the isoelectric point of the protein. Applicant respectfully submits that Nakayama, as with the other references, fails to describe or suggest a composition that includes one or more viscosity-lowering protein(s) that is moderately hydrolyzed and capable of lowering the viscosity of the viscous soluble fibers in the composition before it is orally or enterally administered to a subject such that the composition is less viscous than the same composition in which the viscosity-lowering protein is absent, as set forth in the present claims. Thus, Nakayama fails to teach or suggest all the elements of the claimed invention. Accordingly, Applicant respectfully requests that the §103(a) obviousness rejection in view of Nakayama be reconsidered and the rejection be withdrawn.

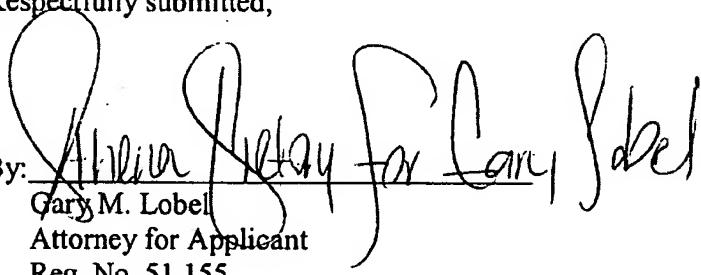
The above comments are presented to overcome the Examiner's anticipation rejection based on all the cited primary references are incorporated herein. Applicant respectfully submits

that the present invention, as claimed herein, is neither anticipated by nor rendered obvious in view of the Bell, Jaussan, Ohta, Heath, Shimizu, Mallangi, Gunter, Wittwer and Nakayama references. Under the decision by the Court of Appeals for the Federal Circuit in KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007), there must be a reason for a person of ordinary skill in the art to combine the elements claimed in order for there to exist a finding of obviousness. As set forth above, there is no reason to selectively consider the references or to combine or use their teachings as suggested in the office action.

**CONCLUSION**

For at least the reasons set forth above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

Respectfully submitted,

By:   
Gary M. Lobell  
Attorney for Applicant  
Reg. No. 51,155

Nestlé HealthCare Nutrition  
12 Vreeland Road, 2<sup>nd</sup> Floor  
Florham Park, NJ 07932  
(973) 593-7553

Dated: July 16, 2009